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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,459	01/25/2002	Joseph Nolfo	VB0038 (NP)	9721
23914	7590	11/14/2003	EXAMINER	
STEPHEN B. DAVIS			QUAN, ELIZABETH S	
BRISTOL-MYERS SQUIBB COMPANY				
PATENT DEPARTMENT			ART UNIT	
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DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,459

Applicant(s)

NOLFO ET AL.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10162003. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 49, 50, 59, 60, 70, and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation of the explosion proof shield defining a "closed" interior space is not support by the drawings, specification, or claims. In fact, the drawings and specification reveal a small gap near the top of the explosion proof shield, such that the interior space is not closed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 42-45, 48, 52-55, 58, 63-66, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,976,470 to Maiefski et al.

Maiefski et al. disclose an apparatus (10) for performing parallel reactions under pressure (Fig. 1). The apparatus comprises two sets (12) of an array of reaction vessels (38) each set

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comprising at least two rows of reaction vessels, six solvent sources (16), and a fluid manifold (14) (Fig. 1; Col. 7, lines 14-16 and 26-28; Col. 9, line 5-Col. 13, line 36). Each of the vessel sets, whether in different reaction blocks or different rows of a single reaction block, has more than reaction vessel (Fig. 1). The fluid manifold comprises a source selection portion (46); fluid distribution portion formed at the surface of the upper manifold plate (92), gasket (96), and lower manifold plate (98); and valve portion (104) interposed between the source selection portion and fluid distribution portion (Figs. 5 and 7). The source selection portion comprises means for selecting one of the fluid sources and connecting the selected source to the valve portion, comprising an actuator (74) and rotary valve member (66) (Col. 9, line 5-Col. 13, line 36). The source selection portion also comprises a pressure relief valve (80), which includes a pressure relief passageway (73) to release back-pressure within the manifold (Col. 9, line 58-Col. 10, line 15). The valve (80) also facilitates connection between the means for selecting one of the fluid sources and connecting the selected source to the valve portion (Col. 9, line 58-Col. 10, line 26). The rotary valve member is a multiple-way fluid control valve comprising a six-way fluid control valve (Col. 9, line 5-Col. 10, line 26). Since the selecting means is a six-way fluid control valve, which is one more than a five-way fluid control valve, the teaching of a six-way fluid control valve meets the limitation of a five-way fluid control valve. The fluid distribution portion comprises a plurality of distribution channels (94) and means for separately connecting each of the distribution channels with each of the reaction vessels in different reaction blocks or different rows/columns of a single reaction block, such as pipette (32,42) (Fig. 1; Col. 10, line 27-Col. 13, line 36). The pipette may be considered a part of the fluid distribution portion since the syringe is contained in the fluid distribution portion (Fig. 8). Alternatively, the interior of the

pipette may be considered distribution channels and the needle itself may be considered the means for connecting the distribution channels with each of the reaction vessels. Each pipette has a check valve (146) to prevent backflow (Col. 11, line 31-Col. 13, line 36).

The valve portion comprises a plurality of independently actuatable valves each of which is associated with a different fluid distribution channel formed in the fluid distribution portion (Figs. 5 and 7). When actuated each of the valves connect the source selecting means in the source selection portion and the associated fluid distribution channel in the fluid distribution portion. It is noted the language independently actuatable, in which -able is defined as capable of or fit for and actuate is defined as to put into mechanical action or motion or to move to action, affords the reasonably broad interpretation of the valves have the capability of being independently actuated or put into motion, such that the valves does not have to be physically be performing independently actuatable to be independently actuatable. The apparatus of Maiefski et al. is controlled by a programmable computer (26), allowing the possibility of the valves being independently actuatable (Col. 7, line 3-6). Furthermore, dispensing is performed substantially simultaneously or the valves may become jammed, indicating that valve actuating may be performed at different times independent of other valves (Col. 5, lines 7-20; Col. 11, lines 26-30).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 46, 56, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,976,470 to Maiefski et al. in view of U.S. Patent No. 6,251,343 to Dubrow et al.

Maiefski et al. disclose a septum sealing each of the reaction vessels. Maiefski et al. fail to disclose the fluid distribution portion comprising a means for separately sealing each of the reaction vessels with fluid distribution channels. Dubrow et al. disclose the needle of a syringe (252) inserted into a stopper (256), which creates a positive seal with the reaction vessel (Col. 11, line 56-Col. 12, line 27). The stopper also prevents the needle from being inserted too deep within a reaction vessel and allows an insertion angle of up to 15 degrees normal to the plane of

the top surface of the reaction block without adversely effecting the sealing ability of the dispensing device with the reaction vessel (Col. 11, line 56-Col. 12, line 27). The stopper may be shaped such that a secondary seal is provided (Col. 11, line 56-Col. 12, line 27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Maiefski et al. to substitute the septum above the reaction vessel to have the fluid distribution portion comprising stopper means for separately sealing each of the reaction vessels with fluid distribution channels as in Dubrow et al. to create a positive seal with the reaction vessel, prevent the needle from being inserted too deep within the reaction vessel, allow insertion angle of up to 15 degrees normal to the plane of the top surface of the reaction block without losing sealing effectively, and allow the opportunity of providing a second seal, if desired.

9. Claims 46, 47, 52, 56, 57, 62, 67, 68, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,976,470 to Maiefski et al. in view of U.S. Patent No. 5,874,048 to Seto et al. or U.S. Patent No. 6,342,185 to Dahl et al. or U.S. Patent No. 6,576,196 to Akporiaye et al. or U.S. Patent No. 5,866,342 to Antonenko et al.

Maiefski et al. disclose a septum sealing each of the reaction vessels. Maiefski et al. fail to disclose the fluid distribution portion comprising o-ring means for separately sealing each of the reaction vessels with fluid distribution channels. However, substituting the septum sealing each of the reaction vessels with an o-ring around the end of the fluid distribution portion is very well known. Seto et al. disclose an o-ring (30) fitted on the lower end of the periphery of the pipette to provide air-tight sealing (Col. 4, lines 38-48). Dahl et al. disclose an o-ring (28) around the end of the fluid distribution portion to provide pressure tight seal (Col. 7, lines 2-30).

Aporiaye et al. disclose an o-ring (30) for sealing reaction vessels and directing fluid flow in the proper path (Col. 8, lines 43-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Maiefski et al. to substitute the septum above the reaction vessel to have the fluid distribution portion comprising stopper means for separately sealing each of the reaction vessels with fluid distribution channels as in Seto et al. or Dahl et al. or Akporiaye et al. to provide pressure tight seal between the reaction vessel and fluid distribution portion and direct fluid along the proper path.

Maiefski et al. fail to disclose a temperature sensing means in which reaction vessels are adapted to receive. However, it would have been obvious to one having ordinary skill in the art to include a temperature sensing means in Maiefski et al. to monitor the temperature within reaction vessels as taught by Dahl et al. or Akporiaye et al. or Antonenko et al.

10. Claims 49, 50, 59, 60, 70, and 71 are rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,976,470 to Maiefski et al. in view of U.S. Patent No. 5,324,483 to Cody et al. or U.S. Patent No. 4,810,471 to Wachob et al.

Maiefski et al. disclose means for connecting the selected fluid source with the reaction vessels, which would be within the interior space of the explosion proof shield had the apparatus included one. Maiefski et al. do not disclose the apparatus comprising an explosion proof shield defining a closed interior space within which the reaction vessels are situated. However, it is very well known to interpose an explosion proof shield between the base and fluid manifold, defining an interior space within which the reaction vessels are situated, to protect the reaction vessels from the environment to maintain a certain pressure in the confined environment of the reaction vessels as necessary to perform an assay. Cody et al. disclose an explosion proof shield

(20) made of transparent materials such glasses or plastics that would allow substantially high pressurization of the reaction vessels as required by common organic syntheses without hazards of explosions such as breakage of materials (see Figs. 1-10; Col. 9, lines 16-61). Ports are located on the exterior surface of the shield (20) to allow fluid access into the interior space of the shield (20) (see Figs. 1-10). Wachob et al. also disclose an explosion proof shield (12) for maintaining a vacuum within its interior, which houses tubes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Maiefski et al. to provide the explosion proof shield as in Cody et al. or Wachob et al. to allow pressurization or evacuation of the reaction vessels as required by certain assays without hazards of explosions.

11. Claims 51, 61, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,976,470 to Maiefski et al.

None of the previously cited references disclose valve stems with different heights. However, it is very well known to use valve stem of different heights for different purposes in the system. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use different stem heights for each of the valves for distinguishing valves associated with different reaction vessels and distribution channels, which have different lengths from the source selection portion to different reaction vessels. It is further noted that one would expect variations in valve stem heights even through mechanical production of the valve stems.

Response to Arguments

12. Applicant's arguments with respect to claims 42-73 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding
d be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1600~~ 1700